K 081541

510(k) SUMMARY
ASCLEPION LASER TECHNOLOGIES GmbH
Dermablate Effect

FEB 23 2009

This 510(k) summary of safety and effectiveness for the Asclepion Laser Technologies GmbH Dermablate Effect is submitted in accordance with the requirements of 21 CFR 907.92 and follows Office of Device Evaluation Guidance concerning the organization and content of a 510(k) summary.

Applicant:	ASCLEPION LASER TECHNOLOGIES GmbH Bruesseler Str. 10 07747 Jena, Germany
Contact Person:	Mrs. Antje Katzer Product Management and International Regulatory Affairs
Phone: Fax: e-mail:	+49 3641 77 00 309 +49 3641 77 00 302 antje.katzer@asclepion.com
Preparation Date:	February 13th, 2009
Device Name:	Dermablate Effect
Common Name:	Dermablate Effect
Classification Name:	Instrument, surgical, powered, laser 79-GEX 21 CFR 878.481
Equivalent Devices:	MCL 30 Dermablate Lux2940 Erbium Fractional Handpiece Profile ProFractional Handpiece Photosilk Plus Cellactor SC1 D-Actor Vibration Massage System
Device Description:	The Dermablate Effect is a pulsed Er:YAG laser emitting a wavelength of 2940 nm, that can optionally be equipped with a pulsed light module (APL) and an acoustic wave module (AW).

Intended Use:	The Dermablate Effect Er:YAG laser with handpiece of larger spot sizes is intended for use for coagulation, vaporization, ablation or cutting of soft tissue (skin) in dermatology, plastic surgery, oral surgery and ophthalmology (skin around the eyes). The Dermablate Effect Er:YAG laser with fractional handpiece is intended for dermatological and skin resurfacing procedures. The Dermablate Effect can be equipped optionally with the following modules: Asclepion Pulsed Light (APL) and Acoustic Wave (AW). The Asclepion Pulsed Light is intended for permanent hair reduction, treatment of vascular and pigmented lesions and inflammatory acne. The Acoustic Wave is intended for the activation of connective tissue.
Comparison to:	The Dermablate Effect is substantially equivalent to the MCL 30 Dermablate (with regard to the Er:YAG laser module with handpiece of larger spotsizes), to the Lux2940 Erbium Fractional Handpiece and the Profile ProFractional Handpiece (with regard to the Er:YAG laser module with fractional handpiece) to the Photosilk Plus (with regard to the APL module) and to the class 1 products Cellactor SC1 and D-Actor 200 (with regard to the AW module) with the same principles of operation, and the same indications for use.

Nonclinical Performance Data: None

Clinical Performance Data: Fractional Er:YAG histological report of Prof. D. Cassuto

Conclusion:	The Dermablate Effect is another safe and effective device for coagulation, vaporization, ablation, cutting of soft tissue, for fractional dermatological and skin resurfacing procedures, for permanent hair reduction, the treatment of vascular and pigmented lesions and inflammatory acne and for the activation of connective tissue.

Additional Information : Software Description

Tables of comparison and 510(k) summaries for D-Actor 200 Vibration Massage System, Lux2940 Erbium Fractional Handpiece, Profile ProFractional Handpiece

Fractional Er:YAG histological report of Prof. D. Cassuto

Biocompatibility test reports for all handpieces

Professional User Guide with treatment parameters for different applications in all modules

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Asclepion Laser Technologies GmbH
% Mrs. Antje Katzer
Product Management and International
Regulatory Affairs
Bruesseler Str. 10
07747 Jena, Germany

FEB 23 2009

Re: K081541
Trade/Device Name: Dermablate Effect
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX, ISA
Dated: February 16, 2009
Received: February 18, 2009

Dear Mrs. Katzer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments; or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K081541

Device Name: Dermablate Effect

Indications for Use:

The Dermablate Effect Er:YAG laser with handpiece of larger spot sizes is intended for use for coagulation, vaporization, ablation or cutting of soft tissue (skin) in dermatology, plastic surgery, oral surgery and ophthalmology (skin around the eyes).

The Dermablate Effect Er:YAG laser with fractional handpiece is intended for dermatological and skin resurfacing procedures.

The Dermablate Effect can be equipped optionally with the following modules: Asclepion Pulsed Light (APL) and Acoustic Wave (AW).

The Asclepion Pulsed Light is intended for permanent hair reduction, treatment of vascular and pigmented lesions and inflammatory acne.

The Acoustic Wave is intended for the activation of connective tissue.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of ~~CDRH, Office of~~ Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081541